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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,713	07/01/2003	David A. Tirrell	CIT1460-2	3724

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EXAMINER

GUZO, DAVID

ART UNIT PAPER NUMBER

1636

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/612,713	Applicant(s) TIRRELL ET AL.	
	Examiner David Guzo	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,8,10-12 and 14-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,8,10-12 and 14-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/16/01</u> | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Abstract

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because the abstract is in two paragraphs. Correction is required. See MPEP § 608.01(b).

35 USC 101 Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-5, 7-8, 10-12, 14 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-5, 6, 8, 10-11, 13-14 of prior U.S. Patent No. 6,586,207. This is a double patenting rejection.

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by RajBhandary (US 5,879,905, cited by applicants).

Both applicants and RajBhandary (See whole document, particularly the Abstract, columns 1-2, 8 and claims 1-9) recite a recombinant vector comprising a polynucleotide sequence encoding an aminoacyl-tRNA synthetase for a selected amino acid and a polynucleotide encoding a polypeptide molecule of interest (which can be methionyl-tRNA transformylase) and host prokaryotic cells comprising said vectors. RajBhandary therefore teaches the claimed invention.

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Duewel et al. (Cited by applicants).

Both applicants and Duewel et al. (Biochemistry, 1997, Vol. 36, pp. 3404-3416, see whole article, particularly the Abstract and p. 3411) recite a modified polypeptide

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molecule (phage lysozyme) wherein a selected amino acid (methionine) is replaced with a desired amino acid analogue (TFM). It is noted that the polypeptide is claimed in a product by process context. Since it appears that the product recited by Duewel et al., although prepared by a different method, would be indistinguishable, absent evidence to the contrary, from the same polypeptide prepared by the claimed method, the instant rejection is appropriate (See MPEP 2113 for guidelines for examination of product-by-process claims). Duewel et al. therefore teaches the claimed invention.

Claims 17-18, 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Dardel et al.

Both applicants and Dardel et al. (J. Bacteriol., 1984, Vol. 160, No. 3, pp. 1115-1122, see whole article, particularly the Abstract, Materials and Methods section on p. 1115-1116) recite a recombinant vector comprising a polynucleotide sequence encoding an aminoacyl-tRNA synthetase (methionyl tRNA synthetase), a polynucleotide encoding a polypeptide molecule of interest (i.e. amp or tet resistance genes) and host auxotroph cells (*E. coli*) comprising said vector. Dardel et al. therefore teaches the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17-18, 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Tao et al. (cited by applicants).

Both applicants and Tao et al. (U.S. Patent 6,221,640, issued 4/24/01, filed 5/14/97, see whole document, particularly columns 15, 22-25, Example 4, column 47) recite a recombinant vector comprising a polynucleotide sequence encoding an aminoacyl-tRNA synthetase (which can be methionyl tRNA synthetase), a polynucleotide encoding a polypeptide molecule of interest and host auxotroph cells (which can be bacterial, yeast, mammalian, etc.) comprising said vector. Tao et al. therefore teaches the claimed invention.

35 USC 103(a) Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tao et al. in view of Smith et al. or Maddon et al.

Applicants claim a recombinant vector comprising a polynucleotide sequence encoding an aminoacyl-tRNA synthetase for a selected amino acid and a polynucleotide sequence encoding a dihydrofolate reductase (DHFR).

Tao et al. (cited above, see whole document, particularly columns 22-24) recites the claimed recombinant vector but does not indicate that the vector contains a sequence encoding DHFR. Tao et al. however does recite that the vector comprising the aminoacyl-tRNA synthetase gene can also contain any selectable marker gene of interest so as to identify transformed cells.

Smith et al. (US 5,627,033, issued 5/6/1997, see whole document, particularly columns 3 and 8) and Maddon et al. (US 5,110,906, issued 5/5/1992, see whole document, particularly columns 13-14) recite that DHFR is a well known and commonly used marker to identify transfected cells.

The ordinary skilled artisan, seeking to choose a selectable marker for use in the vector system disclosed by Tao et al. would have been motivated to select DHFR because DHFR had been a well known and commonly used selectable marker for decades (see Smith et al. and Maddon et al.) and because Tao et al. indicates that any

marker gene could be used in their vectors. It would have been obvious for the ordinary skilled artisan to choose the DHFR gene because the DHFR gene was widely used as a marker gene to select for transfected or transformed cells and could be used in a wide variety of host cells. Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time of applicants' invention, it must be concluded, absent evidence to the contrary, that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

35 USC 112, 2nd Paragraph Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-5 and 16-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is awkward in syntax. Redrafting the claim to recite "The method of claim 1 wherein said host cell is an auxotroph and wherein the auxotrophic host cell is incapable of producing the selected amino acid." would be remedial.

Claim 16 is vague in that it depends from a canceled claim.

Claim 17 (and dependent claims) are vague in that there is no antecedent basis for the term "the selected amino acid".

Claim 19 is vague in the recitation of the phrase "encodes for dihydrofolate reductase protein." Redrafting the claim to recite --encodes dihydrofolate reductase-- would be remedial.

Miscellaneous

Applicants use two different phrases to recite Markush groups in the claims. For example, in claims 3 and 5, applicants recite the language "selected from a group consisting of" and connect the members of the group with "or" while in claims 12, 14 and 21 applicants recite "selected from the group consisting of" and connect the members of the group with "and". It is noted that the Markush language recited in claims 12, 14 and 21 is the traditional language used in Markush claims and applicants are encouraged to use this language. Applicants are encouraged to be consistent in their use of claim language when drafting Markush claims.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
December 31, 2005


DAVID GUZO
PRIMARY EXAMINER
DEC 31 2005